

M e m o r a n d u m**425.0050**

To: Mr. Frank Holby
San Jose District Principal Auditor

September 8, 1978

From: Mary Armstrong
Headquarters - Legal

Subject: D--- D---, Inc.

SR – XX XXXXXX

This is in response to your memorandum of July 14, 1978 concerning a problem which arose in your audit of the referenced taxpayer. In the interim we have also received copies of correspondence between taxpayer and its clients, as well as a document entitled "Protocol: Art. 3-02(H) Orgotein vs. Placebo in Rheumatoid Arthritis."

DDI is a retailer and wholesaler of animal feed and medicine. It is also involved in substantial research and development in the area of drugs for the treatment of human beings.

Your audit revealed that DDI has purchased a drug called orgotein and other related materials under a resale certificate. These were later charged to research and development for clinical testing. You wish to know the correct application of tax to the orgotein and related materials.

Our examination of taxpayer's letters and the Protocol reveal the following fact situation:

In 1975, DDI contracted with various hospitals and clinics to serve as investigators in DDI's study "Orgotein vs. Placebo in Rheumatoid Arthritis." The fee contracted for was an all-inclusive fee per patient of \$1,675 with dropouts prorated appropriately. The fee amount was designed to cover an initial examination of the patient, sixteen weeks of injections, reappraisal examinations, all laboratory work, three ophthalmological examinations by a consultant, and miscellaneous expenses such as mailing forms, laboratory samples, etc.

The drug involved in the study, Orgotein, has been widely used for the treatment of arthritis in horses. It has had limited use in humans for the treatment of both rheumatoid arthritis and osteo-arthritis.

The primary purpose of the study proposed by DDI was to demonstrate, in patients with active rheumatoid arthritis, the anti-inflammatory efficacy of orgotein either as primary therapy or as concomitant therapy with aspirin, aspirin and corticosteroid, or gold plus aspirin. The study proposed by DDI was a 16 week double-blind, placebo controlled study. At least 24 patients were to be studied at each clinic.

During the course of the study, DDI supplied medication in 4mg single use vials, to be reconstituted in DDI special diluent (sodium chloride injection USP, without preservative ph 6.5-7.0). All vials supplied by DDI were code labeled and contained either orgotein (4mg of orgotein and 8mg sucrose) or a placebo (8mg sucrose). The orgotein and placebo were supplied in cartons. Each patient participating in the study was assigned a carton which contained the medication to be given that patient during the course of the study.

In addition to the orgotein or placebo, DDI also supplied propoxyphene (Darvon) to the clinics for the participant's use if necessary. Each investigator was required to maintain records of its distribution and use and patients were required to keep a diary of their daily propoxyphene consumption.

Each patient's participation in the study was on a voluntary basis without payment by either DDI or the hospital.

DDI's attorney, Mr. D--- B---, contends that orgotein qualifies as a "medicine" under Regulation 1591 despite its experimental usage since it is administered by physicians under contractual agreement with DDI. It is Mr. B---'s opinion that the administration of drugs to participants of DDI's study, by doctors who have been paid by DDI to perform this function is similar to situations found in Business Taxes Law Guide Annotations 425.0040 and 425.0140. Both of these annotations deal with the situation where medicines are sold to companies which contract with physicians who administer the medicines in the medical treatment of other employees. It has been the Board's position that the sale of "medicines" to the companies in this type of situation qualifies as a sale of "medicines" furnished by a licensed physician to his own patients and therefore would be exempt from tax under Regulation 1591(a)(1) through (5).

In our opinion, there are three problems which must be resolved in order to determine the correct application of tax in this situation. The first question is whether or not the experimental nature of the drug, orgotein, precludes its classification as a "medicine" under Regulation 1521. Secondly, it must be determined whether it was proper for DDI to purchase the drugs in question under a resale certificate and finally we must determine whether the drugs were sold, stored, consumed or used in the manner prescribed in Regulation 1591(a)(1) through (5).

We have concluded that the experimental nature of the drug, orgotein, does not preclude its classification as a substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for such use. Although, according to the information contained in the "Protocol" orgotein has not been widely used, we are of the opinion that it can still be considered a substance or preparation "commonly recognized" for use as a "medicine." As such, when "orgotein" is sold in the manner prescribed in Regulation 1591(a)(1) through (5), it will be exempt from tax as a "medicine."

In order to determine whether the orgotein was sold, stored, used or consumed in the manner prescribed in Regulation 1591(a)(1) through (5), the various transfers of property must be broken down.

As we understand it, DDI purchased "orgotein and related materials combined for experimental purposes" from W--- C--- Corporation under a resale certificate. These purchases were later changed to research and development when they were used in the course of the orgotein study. The orgotein and placebo, as well as the diluent, were then sent to the various clinics participating in the study. Each clinic was paid an agreed upon fee to administer orgotein or the placebo and perform other duties as required. We have assumed for purposes of analysis that what is meant by "orgotein and related materials" is the orgotein, sucrose solution and the diluent.

The question arises as to whether DDI can be considered to have resold the orgotein and related supplies to anyone under these facts. We are of the opinion that these items were not "resold" since they were furnished free of charge to the clinics for use in the experiment and were in fact essential to the success of the experiment. All information concerning the volunteers who were being treated was sent to DDI for evaluation. Thus under the facts presented, a "sale" within the meaning of Revenue and Taxation Code Section 6006 did not take place and the drugs and related materials should not have been purchased under a "resale" certificate.

If the sale of orgotein and related supplies to DDI was not a sale for resale, it is necessary to determine whether the sale, storage, use or other consumption of these items was in a manner prescribed in Regulation 1591(a)(1) through (5) so as to make the sales to, and use by, DDI exempt sales and purchases of "medicines."

Regulation 1591 (a)(1) through (5) provides:

"Tax does not apply to sale of medicines for the treatment of a human being which medicines are:

- (1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on

prescription filled by a registered pharmacist in accordance with law, or

(2) furnished by a licensed physician and surgeon, dentist or podiatrist to his own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician and surgeon, dentist or podiatrist, or

(4) sold to a licensed physician and surgeon, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof.”

We are of the opinion that this situation is similar to one in which a company may purchase medicine to be administered to its employees by a contracting physician. Although in the case of DDI the reason orgotein and related supplies were purchased was for experimental purposes, the situation is somewhat similar to that described in Annotation 425.0440. There it was found that when influenza vaccine was purchased under a general prescription and given to employees who desired to be vaccinated and consented to be patients of the doctor with whom the center contracted to prescribe and administer or supervise the administration of the vaccine, the vaccine was considered to be prescribed for the treatment of human beings by a person authorized to do so and furnished by a licensed physician to his own patients for treatment of such patients.

In the case of DDI, the doctors being paid to participate in the orgotein study can be considered to be agents of DDI. Therefore, when orgotein was purchased from W--- by DDI for the purpose of being given to the doctors participating in the study to be prescribed for specific patients, it is our opinion that the “medicine” was “prescribed for the treatment of a human being...” and “furnished by a licensed physician and surgeon...to his own patient for treatment of the patient.” Thus the sale of orgotein to DDI was of a “medicine” in the manner prescribed in 1591(a)(1) and (2) and tax will not apply to such sales.

We do not consider this situation to be similar to one in which a manufacturing company gives away samples and is considered to have self-consumed the samples. In the situation before us, the use of the property made by the physician (furnishing “medicines” to the patient) is attributable to the company, for whom he is acting as agent. In the situation involving samples, the use of the property by the physician is not attributable to the company and the company’s use

of the property in transferring the property to the physician is not a use described as exempt under paragraphs (a)(1) through (5) of the regulation.

If you have further questions concerning this matter, I will be happy to discuss them with you.

MCA:ba